- 1 1. (Currently Amended) A pharmaceutical composition comprising:
- a) from about 0.1% to about 50 % by weight of lamotrigine or acid
- 3 addition salt thereof;
- b) from about 15.5% to about 70% by weight of microcrystalline cellulose;
- 6 c) from about 0.1% to about 14.5% by weight of sodium starch glycolate;
- 7 and
- from about 0.1% to about 4.5% by weight of polyvinylpyrrolidone.
- 1 2. (Original) The pharmaceutical composition according to claim 1, further comprising from
- 2 about 0.1% to about 14.5% by weight of lactose.
- 1 3. (Cancelled).
- 1 4. (Cancelled).
- 1 5. (Original) The pharmaceutical composition according to claim 2, wherein the
- 2 composition comprises about 20% to about 70% by weight of microcrystalline cellulose,
- 3 about 0.1% to about 10% by weight of sodium starch glycolate, about 0.1% to about 3% by
- 4 weight of polyvinylpyrrolidone, and about 0.1% to about 10% by weight of lactose.
- 1 6. (Original) The pharmaceutical composition according to claim 1, wherein the sodium
- 2 starch glycolate is intragranular.
- 1 7. (Original) The pharmaceutical composition according to claim 1, wherein the sodium
- 2 starch glycolate is extragranular.
- 1 8. (Original) The pharmaceutical composition according to claim 1, wherein the
- 2 composition is a tablet.
- 9. (Original) The pharmaceutical composition according to claim 1, wherein at least 80% by
- 2 weight of the lamotrigine or the acid addition salt thereof dissolves within 10 minutes.
- 1 10. (Original) The pharmaceutical composition according to claim 1, wherein at least 90% by
- 2 weight of the lamotrigine or the acid addition salt thereof dissolves within 30 minutes.

- 1 11. (Original) The pharmaceutical composition according to claim 1, wherein the
- 2 composition is stable after three months storage at 40°C and 75% RH with at least 98% of the
- 3 lamotrigine or acid addition salt thereof remaining after three months.
- 1 12. (Original) A process for preparing a pharmaceutical composition, the process comprising
- wet granulating a composition that includes:
- a) from about 0.1% to about 50 % by weight of lamotrigine or acid addition salt thereof;
 - b) from about 15.5% to about 70% by weight of microcrystalline cellulose;
- 6 c) from about 0.1% to about 14.5% by weight of sodium starch glycolate; and
- 7 d) from about 0.1% to about 4.5% by weight of polyvinylpyrrolidone.
- 1 13. (Original) The process according to claim 12, wherein the pharmaceutical composition
- 2 further comprises from about 0.1% to about 14.5% by weight of lactose.
- 1 14. (Cancelled).

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- 1 15. (Cancelled).
- 1 16. (Original) The process according to claim 13, wherein the composition comprises about
- 2 20% to about 70% by weight of microcrystalline cellulose, about 0.1% to about 10% by
- 3 weight of sodium starch glycolate, about 0.1% to about 3% by weight of
- 4 polyvinylpyrrolidone, and about 0.1% to about 10% by weight of lactose.
- 1 17. (Cancelled).
- 1 18. (Currently Amended) The process according to claim 12 or 13, wherein the
- 2 lamotrigine or its acid addition salt, microcrystalline cellulose, and sodium starch glycolate,
- and polyvinylpyrrolidone and/or lactose are blended and then granulated with water.
- 1 19. (Currently Amended) The process according to claim 12 or 13, wherein the lamotrigine or
- 2 its acid addition salt, microcrystalline cellulose, and sodium starch glycolate and/or lactose
- are blended and then granulated with an aqueous solution of polyvinylpyrrolidone.
- 1 20. (Currently Amended) The process according to claim 12 18, further comprising
- 2 screening the wet mass to obtain granules.

- 1 21. (Cancelled).
- 1 22. (Original) The process according to claim 20, further comprising drying and sieving the
- 2 granules.
- 1 23. (Cancelled).
- 1 24. (Original) The process according to claim 22, further comprising compressing the
- 2 granules to form tablets.
- 1 25. (Cancelled).
- 1 26. (Currently Amended) The process according to claim 12, wherein the sodium starch
- 2 glycolate is <u>either or both</u> intragranular <u>or extragranular</u>.
- 1 27. (Cancelled).
- 1 28. (Original) A method of treating a medical condition responsive to lamotrigine, the
- 2 method comprises administering a pharmaceutical composition of lamotrigine, the
- 3 composition comprising:
- from about 0.1% to about 50% by weight of lamotrigine or acid addition salt thereof;
- 6 (b) from about 15.5% to about 70% by weight of microcrystalline cellulose:
- 8 (c) from about 0.1% to about 14.5% by weight of sodium starch glycolate; 9 and
- 10 (d) from about 0.1% to about 4.5% by weight of polyvinylpyrrolidone.
- 1 29. (Original) The method according to claim 28, wherein the pharmaceutical
- 2 composition further comprises from about 0.1% to about 14.5% by weight of lactose.